HFL-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1208B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

February 20, 1997 WL-12-7

Peter P. Darula
Owner
Vitalizer 2000
2409-D LaCosta Avenue
Carlsbad, CA 92009

Dear Mr. Darula:

During an inspection of your facility conducted on December 5, 1996, our investigator determined that your firm is commercially marketing a self-activated crystal stimulator. Your literature indicates that this device stimulates acupuncture, acupressure and reflexology points anywhere on the body and is highly effective in relieving discomforts caused by such ailments as sciatica, arthritis, rheumatism, carpel tunnel, tennis elbow, headaches, back pain, sore joints and muscle pain. Therefore, your "Vitalizer 2000" self-activated crystal stimulator is a medical device as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (Act).

These devices are adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) and do not have an approved application for premarket approval in effect pursuant to Section 515(a), or an approved application for investigational device exemption under Section 520(g).

Additionally, these devices are misbranded within the meaning of Section 502(o) in that the device was manufactured, prepared, or propagated, compounded,or processed in an establishment not duly registered under Section 510, was not included in a list required by Section 510(j), and a notice or other information respecting these devices were not provided to the FDA as required by Section 510(k).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory

action being initiated by the Food and Drug Administration without further notice. Such actions includes, but is not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard
Irvine, California 92715-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814